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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,391	07/22/2003	Mark Galloway	11147.5	6825

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,391	GALLOWAY ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2007 and 03 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 5/25/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-9 and 23-26 are the current claims hereby under examination.

Drawings

The objection to the drawings has now been withdrawn because of applicant's submission of a proper Fig. 12.

The drawings received on 5/25/2007 and 1/3/2007 have now been accepted and entered.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Response to applicant's arguments:

Applicant's arguments, filed 5/25/2007, with respect to the rejection of claims 1-9 and 23-26 under ***35 USC § 101 and 35 USC § 112*** have been fully considered and are persuasive. Therefore the rejection of claims 1-9 and 23-26 under ***35 USC § 101 and 35 USC § 112*** has been withdrawn.

The following is a rejection being newly applied.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 112, first paragraph (Enablement)

Claims 8, 9, 12-16, 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The standard for determining whether the specification meets the enablement test was first stated in *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), and asks if the experimentation needed to practice the invention undue or unreasonable.

The claimed invention is enabled if any person skilled in the art can make and use the invention without undue experimentation. The focus is on 'undue' rather than on 'experimentation' (*In re Wands*, at 737, 8 USPQ2d at 1404; see also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)).

A patent need not teach what is well known in the art (In re Buchner, 929 F.2d 660, at 661, 18 USPQ2d 1331, at 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, at 231 USPQ 81, at 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, at 1463, 221 USPQ 481, at 489 (Fed. Cir. 1984)).

Determining whether claims are sufficiently enabled by the specification is based on underlying findings of fact. *In re Vaeck*, 947 F.2d 488, at 495, 20 USPQ2d 1438, at 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, at 576, 224 USPQ 409, at 413 (Fed. Cir. 1984).

The Breadth of the Claims

The claims are overly broad because the claims encompass any type of existing manifested and latent malady for diagnostics and treatment, which includes diseases which do not have any medically recognized treatments.

The Nature of the Invention, and the Level of One of Ordinary Skill

As it is with many inventions in the biotechnology arts, the art is multidisciplinary. Applicants' claimed invention relates to a number of core technologies and scientific concepts including internal medicine, acupuncture, electrophysiology, physics, pathology, cardiology and bioinformatics, to name a few. In particular, the claimed invention requires the ability for diagnosing and treating existing manifested and latent maladies within a patient, which includes any malady and accurate analytical

techniques (quantitative and qualitative), and the demonstration of data analysis for conclusions that are predictive in disease assessment and treatment for any person.

Those of skill in the art have a strong understanding of the inter-relationship between each of the disciplines and the functional and physical limitations of the claimed invention. Where the specification fails to provide guidance, the person of ordinary skill in the art would be capable of identifying the appropriate art for the requisite guidance. Accordingly, those of ordinary skill in the art would understand that certain amounts of experimentation with similarly related inventions may be required. For example, as it relates to Applicants' claimed invention, one of ordinary skill in the art may find that some experimentation is necessary in deciding what type of resistance correlates with what type of disease. Since the invention is drawn to every possible malady an exceptionally large amount of experimentation would be necessary for correlating accurate results with particular ailments.

The Amount of Guidance, and the Existence of Working Examples

In the *Background of the Invention* (pages 2-5), Applicants summarize concepts in Meridian Stress Assessments and the evolution of electrodiagnosing.

In the *Summary of the Invention* (pages 6-9), Applicants indicate that the invention is directed to a method for advancing alternative medicine treatment methods, and particularly treatment methods utilizing Galvanic Skin Response (GSR) and/or electro-acupuncture by Voll (EAV) devices.

In the *Detailed Description of the Invention*, Applicants summarize the development of the invention along with general ideas about how meridian points work and the correlation between developed maladies and alterations to measurable resistance through Electrodermal Screening. Applicant's further summarize the general idea of a working computer, which executes general software instructions for diagnosing and selecting from pre-loaded treatments, an optimized treatment.

Applicants continue by alleging that the inventive system is capable of diagnosing and treating any type of malady. Applicant's fail to provide any working examples showing data, which correlates any measurable resistance to an existing

malady. Furthermore, one of ordinary skill in the art would not immediately know which resistance levels correlate with which maladies. Therefore, one of ordinary skill in the art would turn to the specification, which provides absolutely no working examples for these correlations nor any data, such as tables, which demonstrate any standards for said correlations.

Applicants further allege the ability to diagnose a whole range of ailments as those listed in a table, for example, in Figs. 11, 12, and 15, but do not demonstrate how any of said maladies are diagnosed by having particular levels of resistance.

The State of the Prior Art and the Level of Predictability in the Art

A number of scientific challenges are present in understanding a correlation between the skin resistance, and the diagnosis of existing manifested and latent maladies. Generally, there are number of art-related disclosures that illustrate that the art as it pertains to the claimed invention is unpredictable.

Semizzi et al. teaches how electrodermal instruments, which have been used for at least 40 years by meany non-health professional and also some doctors, have only gone through a few rigorous studies, which have investigated double-blindly these procedures and have produced controversial results. In the study conducted by Semizzi et al., they concluded that their machine used can have, under rigorous conditions, a reliable diagnostic value for respiratory allergies.

Similarly, Pearson et al. was testing whether skin impedence at each of three acupuncture points is significantly lower than at nearby sites on the meridian and off the meridian. Pearson et al. concluded that none of the three acupuncture points tested has lower skin impedance than at either of the nearby control points and suggested that caution is warranted when developing, using, and interpreting results from electrodermal screening devices.

Similarly, Ko et al. teaches in a survey completed by 380 families, which 22% of the respondents used some form of unproven or disproven diagnostic modality, such as electrodermal skin testing for testing for food allergins, whom reported poor efficacy for diagnostics and treatment.

Barrett, Stephen, M.D. provides a detailed review on Electrodiagnostics. Barret describes the history of such machines and how they work ranging from companies who produce or sponsor them such as The Occidental Institute Research Foundation and BioMeridian. Barrett further reviews the legal status of such machines and states that the FDA had determined that EDS machines such as Dermatron and Accupath 1000 posed significant risk. Moreover, Barrett reviews the enforcement action taken by the FDA agains companies who distribute or market such machines. Barrett concludes by stating that EAV devices should be confiscated and that practitioners who use them should be delicensed.

The Quantity of Experimentation

Based on the art cited above, the unresolved issues of the rigorous testing and establishment between levels of resistance and particular diseases or maladies would make the required level of experimentation for establishing such correlations for each known malady quite undue.

Accordingly, in order to enable the invention as claimed, one of ordinary skill in the art would have to resort to undue experimentation.

Conclusions

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

Lori A. Clow
Primary Examiner
9/4/07